Novartis' $678 Million Settlement Sets Guideposts for Life Sciences Industry Speaker Programs

Skadden

08 / 24 / 20

If you have any questions regarding the matters discussed in this memorandum, please contact the attorneys listed on the last page or call your regular Skadden contact.

One Manhattan West
New York, NY 10001
212.735.3000

Novartis Pharmaceuticals Corporation[1] (Novartis) recently entered into a civil settlement agreement with the Department of Justice (DOJ) to resolve allegations that the company paid health care practitioners (HCPs) who spoke at or attended Novartis speaker events, roundtables, speaker training meetings or "lunch and learns" to induce them to prescribe Novartis drugs, in violation of the Anti-Kickback Statute (AKS) and False Claims Act (FCA).[2]

The focus of the $678 million settlement, reached on July 1, 2020, was conduct that the DOJ has become adept at investigating and that is arguably the highest-risk marketing practice in the life sciences industry: paying HCPs, who often prescribe the company's products, to promote those products to other physicians. Beyond the headline-grabbing civil fines and penalties, the settlement includes an extensive corporate integrity agreement (CIA) with the Office of the Inspector General of the Department of Health and Human Services (HHS-OIG). Companies with speaker programs should carefully review the Novartis settlement and CIA, and consider whether the requirements therein provide an appropriate benchmark for their programs.

Key Takeaways

The settlement reflects the DOJ's continued enforcement focus on a common industry marketing program: physician-led speaker programs.

- The DOJ continues to focus on established issues, including the number and type of program attendees, the nature of venues and falsification of program records.
- The speaker program review also expanded into new areas, and the settlement ultimately focused on some conduct that had not previously been fully explored through litigation or settlements, including internal budgeting decisions and attendee return-on-investment (ROI) analyses.
- The CIA required "fundamental changes to [Novartis'] speaker program"[3] by restricting the company's ability to engage in such programs, limiting speaker remuneration to below the industry standard and imposing strict accountability standards.

[1] Novartis Corporation, the U.S. corporate arm of Novartis AG, entered into the CIA. For ease of reading, Novartis Corporation also is referred to as "Novartis."

[2] Novartis recently entered into a separate settlement with the U.S. Attorney's Office for the District of Massachusetts relating to the company's relationships with independent charitable foundations. *See* "Novartis Agrees To Pay Over $51 Million To Resolve Allegations that It Paid Kickbacks Through Co-Pay Foundations," U.S. Attorney's Office for the District of Massachusetts, July 1, 2020.

[3] "Acting Manhattan US Attorney Announces $678 Million Settlement of Fraud Lawsuits Against Novartis Pharmaceuticals Corporation for Operating Sham Speaker Programs Through Which It Paid Over $100 Million to Doctors To Unlawfully Induce Them To Prescribe No," U.S. Attorney's Office for the Southern District of New York, July 1, 2020.

Novartis' $678 Million Settlement Sets Guideposts for Life Sciences Industry Speaker Programs

A Settlement That Followed Years of Litigation

As is often the case in the life sciences industry, the DOJ's investigation of Novartis was spurred by a *qui tam* complaint filed by a Novartis sales representative in 2011. The DOJ intervened in the case approximately 2 1/2 years later, and the parties engaged in protracted motions practice for nearly a decade. The parties ultimately adjourned a May 2019 trial date and, in July 2020, settled the litigation with a negotiated resolution resulting in Novartis paying a total of $678 million — with $629.8 million in fines, penalties and forfeiture to the U.S. and $48.1 million to various states.

The settlement resolved allegations that Novartis paid HCPs in violation of the AKS and FCA. Although the covered conduct involved speaker programs promoting 10 covered drugs from 2002 to 2011, three of the covered drugs were limited to the time period 2010 to 2011, likely because Novartis previously settled allegations that it provided "illegal remuneration, through mechanisms such as speaker programs," for the three drugs between 2002 and 2009.[4]

As is typical for civil FCA settlements with the U.S. Attorney's Office for the Southern District of New York, Novartis was required to admit and accept responsibility for certain conduct. In part, Novartis admitted that:

- Sales representatives were encouraged to spend their full promotional budget, and their ability to spend the allotted budget was factored into their overall sales performance in annual reviews;
- Sales representatives and their managers had broad discretion to decide which local doctors to nominate as speakers, and Novartis provided sales representatives prescribing data that was used to select high-prescribing doctors;
- Novartis hosted speaker programs at expensive restaurants, often exceeding internal program budget limits, and permitted the consumption of large quantities of alcohol;
- Speaker programs were held at venues with a focus on entertainment, such as sporting events and wine tastings;
- Many speaker programs had little to no educational content, and the same doctors repeatedly attended programs with colleagues or friends and, in some instances, spouses or guests who were not HCPs; and
- Compliance materials suggested emails advocating kickbacks were improper because they ignored the import of written communications, and sales representatives should instead consider using the telephone.

[4] *See* United States' Notice of Partial Intervention and Declination for Purposes of Settlement, *United States ex rel. Novartis Pharma. Corp.*, 2:08-cv-02588-TON Ex. A (E.D. Pa. Sept. 30, 2010).

Novel Speaker Program Controls in CIA

The CIA imposes strict limits and extensive obligations on Novartis' speaker program, many of which are being required for the first time. The CIA permits two types of speaker programs:

1. Internal speaker programs, which must be conducted by Novartis employee HCPs, may be held live at any time.
2. External speaker programs, which are conducted by HCPs who are not Novartis employees, may be conducted only in a virtual format. Although many companies host speaker programs for years following a product release to ensure HCPs are well educated about the product, Novartis' external speaker programs may occur only within 18 months of a newly approved government reimbursed product or indication. Recordings of the virtual programs made during the 18-month period may be made available during and after that time.

The CIA also imposes limits on the remuneration that can be allocated to a newly approved government reimbursed product or indication, and the limits are much lower than many companies' current benchmarks: $100,000 in total remuneration across all external speakers and no more than $10,000 to any given speaker.

These speaker program limitations emphasize the government's general concern that speaker programs may be taking place in the absence of a legitimate educational need. Companies may be conducting programs — and paying remuneration to speakers — at a point in time when relevant HCPs already should know, or otherwise have access to, the relevant product information. Speaker programs thus would not be needed to convey information to prescribing HCPs. Additionally, sales representatives may be hosting programs simply to meet internal requirements, without there being an educational need.

Speaker Selection

Although sales representatives have long been an integral part of companies' sales and marketing efforts, the DOJ took issue with Novartis sales representatives' involvement in the speaker selection process. The settlement agreement includes admissions that Novartis provided prescribing data to sales representatives — which allowed them to identify high-volume prescribers to nominate as speakers — and broad discretion to Novartis' sales representatives and managers to determine which local doctors to nominate as speakers. Although high-prescribing doctors generally have the experience required to speak intelligently about a product on a company's behalf, it is likely that the DOJ's concern stemmed from the fact that high-prescribing doctors may have been selected as paid speakers specifically because they were high prescribers. To curtail such practices, the CIA requires speakers to

be selected based on objective, standardized criteria without any involvement by field sales representatives, a practice that many companies have already adopted.

Venue, Audience and Content of Speaker Programs

In speaker program-related settlements, the DOJ generally analyzes the nature of the venue, the audience and the educational content provided to attendees. According to the DOJ, programs held at sporting events, golf clubs, wine tastings or expensive restaurants are often indicators of a less-than-legitimate program. Similarly, the DOJ has found that programs are suspect when they are short in duration, or include attendees with an inappropriate specialty or who have recently received the relevant educational information. The Novartis settlement included admissions that the company held speaker programs at some of the most expensive restaurants in the United States and that expensive alcohol was served to attendees, often "to the point of intoxication." Medical discussions at the programs were alleged to be minimal, if they occurred at all, and attendees were frequently invited to multiple programs with the same or similar content. Additionally, some employees violated company compliance policies by spending more than the allotted per person budget, and others falsified records to make it appear as though what they spent on a program was less than the actual amount.

The DOJ also emphasized kickbacks to program attendees. Not only did the attendees receive the aforementioned meals and excessive alcohol at expensive restaurants, they were also often permitted to bring spouses or other guests who were not prescribing HCPs. Moreover, in thousands of instances, the company paid for the same group of doctors, often colleagues or friends, to have dinners together repeatedly and sometimes rotated who within the group would speak and receive the honorarium payment.

To address this alleged conduct, the CIA eliminates the traditional speaker program format. Novartis may no longer host speaker programs in restaurant venues or provide alcohol. External speaker programs must be conducted in a virtual format, and Novartis may not organize a gathering outside of an individual HCP's institution or office. Although the CIA does not address appropriate attendees in detail, the settlement agreement indicates that nonprescribing attendees will be met with skepticism.

Analyzing Speaker Programs

Life sciences companies that host speaker programs frequently conduct ROI on attendees to consider whether the programs have the intended educational impact. However, the settlement agreement includes admissions that Novartis calculated ROI based on new prescriptions written by doctor attendees. Although it is unclear whether the DOJ's concern stems only from the fact that numerous prescribers repeatedly attended similar or the same programs in a short period of time, attendee ROI has been highlighted in past DOJ resolutions and is likely to be a focus of future investigations.

Establishing an Effective Compliance Program

In charging a corporation, the DOJ considers a company's implementation of an effective, well-designed compliance program. It is thus not surprising that this settlement agreement alleges that Novartis failed to implement a fully effective compliance program. This alleged failure included monitoring only a small number of speaker programs, providing sales representatives advance notice of upcoming program audits, providing inadequate compliance resources and providing dilatory attention to complaints. Although the settlement agreement did not specify what policies and procedures (and implementation of the same) would have been sufficient to avoid DOJ scrutiny, the CIA provides details into the types of compliance programs companies should consider.

Speaker monitoring programs are common in speaker-related agreements, and the Novartis CIA is no different. HHS-OIG generally requires monitoring personnel to attend a designated number of speaker programs during each reporting period, although the approach has varied. In some instances, the CIA does not establish a required number of audits but notes that HHS-OIG will determine the number of programs to be audited after taking into account the number of speaker programs to be conducted. In other instances, CIAs have required live audits of up to 125 speaker programs related to government reimbursed products. In the Novartis CIA, HHS-OIG required audits of four external speaker programs for each newly approved government reimbursed product or indication. Although this audit requirement is less onerous than previous CIAs, it is likely because the $100,000 remuneration cap imposed by the CIA means that, as a practical matter, Novartis cannot hold a large number of programs.

The CIA also requires Novartis to maintain a disclosure log to record all disclosures, whether or not related to a potential violation of law associated with the federal health care programs or Food and Drug Administration requirements. All disclosures must be logged within two business days of receipt, and the log must state the individual or department responsible for reviewing the disclosure, the status of the internal review and any corrective action taken. Although the CIA does not provide timelines for the completion of an investigation (which would be too onerous for company compliance personnel already handling a number of pertinent matters), the provision is clearly designed to

Novartis' $678 Million Settlement Sets Guideposts for Life Sciences Industry Speaker Programs

address Novartis' "backlog of potential AKS violations"[5] that went unaddressed. Companies should institute policies to ensure that all compliance concerns are investigated and promptly resolved.

The settlement also includes a general admission that Novartis incentivized sales personnel with bonuses tied to growth in local market share. Although neither the settlement nor the CIA prohibits such a compensation structure or provides guidance about what the government considers acceptable, use of incentive compensation as a driver of behavior is a consistent area of DOJ focus. The CIA requires Novartis to develop an incentive compensation restriction program, including designing policies to ensure that financial incentives do not lead to improper promotion or sales and marketing tactics, and implementing mechanisms, where appropriate, to exclude from incentive compensation any sales that may indicate off-label promotion.

The CIA also highlights HHS-OIG's desire for executive-level oversight and accountability. Specifically, the CIA requires a senior Novartis executive to certify to the HHS-OIG that, to the best of his or her knowledge, Novartis complied with the requirements relating to external speaker programs. Should HHS-OIG determine that Novartis or the certifying official failed to comply with the CIA-imposed restrictions, the FCA settlement provides that HHS-OIG may refer the alleged violation to the DOJ to seek injunctive relief against the company and monetary penalties against the certifying official. Such executive-level oversight — even without a certification to HHS-OIG — can help companies ensure that appropriate steps are being taken to address any AKS risks. Novartis also is required to establish an executive financial recoupment program that puts at risk of forfeiture and recoupment an amount equivalent of up to three years of annual performance pay for any executive determined to have been involved in significant misconduct.

Implications

The Novartis settlement addresses what is arguably the highest risk marketing practice in the life sciences industry — speaker programs — and provides significant detail regarding the activities that the DOJ found to be problematic. In light of the settlement, below are some suggestions for specific activities companies should consider reviewing:

- **Needs Assessment.** Companies are increasingly conducting needs assessments to refine their marketing budgets. Although companies need not automatically institute a dual internal/external program track, nor reduce remuneration to the Novartis-specified limits, it is important to implement a rigorous, well-documented process and undergo compliance review to ensure the number of speaker programs conducted is based solely on the need to educate HCPs on new products, new indications or other developments requiring updated information on the company's products. Companies also should reassess whether the total or individual fee cap limit is reasonably necessary based on the assessed needs.
- **Speaker Selection.** Companies should institute objective criteria for selecting speakers. Although having experience with a type of product may be one criterion for selection, companies should ensure that speakers are not selected based on prescribing habits alone.
- **Attendee Credentials.** Companies should consider imposing strict limits on the types of HCPs and HCP staff that can attend programs, with a focus on the types of attendees who need the information for a particular product. A one-size-fits-all policy may not provide the tailored inquiry to determine appropriate attendees suggested by the Novartis settlement.
- **Attendee Frequency.** Companies should consider imposing strict limits on the number of programs (and over what time period within a given geographic area) an HCP or a member of an HCP's staff can attend. In addition to providing written guidelines, companies should consider utilizing automated systems that prevent HCPs and/or HCP staff from registering for the same or a similar event during a specified time period.
- **Venue, Audience and Content.** Companies should ask these key questions to determine whether the venue, audience or content of a speaker program may invite DOJ scrutiny: Does the venue allow for the effective communication of educational information (*e.g.*, private room, low noise level)? Is the venue modest in nature given the geographic location of the program? Are the food and beverage provided appropriate for an educational seminar? Will the provision of alcohol distract from the educational information? Will the attendees benefit from information about the particular product? Has the attendee already attended the same or a similar program? If yes, is there an added benefit to the attendee joining the program again? Was educational information actually conveyed to program attendees? Were the company's compliance policies followed in the selection of the venue and attendees, and in ensuring educational content was disseminated?
- **Attendee ROI.** Companies conducting ROI of speaker programs should carefully consider the need for the analysis, and ensure that it severs any link between the provision of remuneration and prescriptions.
- **Field-Based Involvement.** Companies should consider clearly delineating the role of sales representatives (and others who receive incentive compensation based on territory or regional

[5] Stipulation and Order of Settlement and Dismissal, *United States v. Novartis Pharmaceuticals Corp.*, 11-cv-0071 (PGG) (S.D.N.Y.).

Novartis' $678 Million Settlement Sets Guideposts for Life Sciences Industry Speaker Programs

sales or market share targets) in selecting speakers and program attendees. Companies should consider whether it is necessary for sales representatives and other commercial personnel to be involved in the speaker nomination process.

- **Monitoring and Auditing.** After conducting a rigorous needs assessment, companies should devise monitoring and auditing programs that look at a sufficient number of individual programs and programs in the aggregate, including across therapeutic areas and geography, to ensure compliance with company policies and relevant laws. Companies also should consider whether providing advance notice to sales representatives of an audit may hinder the effectiveness of the monitoring program. Companies also should consider implementing a headquarter-based review of speaker programs to ensure compliance with speaker program policies and relevant laws.
- **Incentive Compensation Structures.** Companies should carefully review incentive compensation structures and implement controls to ensure that incentive compensation awards do not incentivize improper or illegal behavior.
- **Compliance Communications.** Lawyers and compliance professionals should be careful about how they communicate compliance policies to company personnel. It is entirely appropriate to advise personnel to move communications to phone or video conferencing if that is needed to discuss complicated issues and convey nuance, options and strategies to conduct activities in a compliant manner. However, advising people to avoid putting things in writing — without indicating a legitimate need to do so — can raise prosecutorial eyebrows given the possibility the guidance will be misinterpreted as approving improper conduct as long as that conduct is not documented.

Contacts

John T. Bentivoglio
Partner / Washington, D.C.
202.371.7560
john.bentivoglio@skadden.com

Jennifer L. Bragg
Partner / Washington, D.C.
202.371.7980
jennifer.bragg@skadden.com

Maya P. Florence
Partner / Boston
617.573.4805
maya.florence@skadden.com

Avia M. Dunn
Counsel / Washington, D.C.
202.371.7174
avia.dunn@skadden.com

Elizabeth L. Berry
Associate / Washington, D.C.
202.371.7908
elizabeth.berry@skadden.com